

REMARKS

Claims 1-23 and 38-52 are pending in the application. Claims 1, 14, 38 and 47 are currently amended. The amendments do not present any new matter. *See, e.g.*, p. 17, line 8 - p. 18, line 4; Figs. 20-21; (base member includes main portion with a groove configured to receive a support structure). Claims 9, 12, 19, 21, 23, 44 and 46 are withdrawn from consideration. It is respectfully requested that these claims be reinstated upon allowance of the respective independent claims (and any intervening dependent claim) from which they depend. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections / Cited References

Applicants kindly acknowledge that the prior rejections involving U.S. Patent No. 6,692,491 to Phan, U.S. Patent No. 6,771,996 to Bowe and U.S. Patent No. 6,997,925 to Maguire have been withdrawn. Applicants also kindly acknowledge that the final Office Action rejects only claims 38-43, 45 and 47-49 based on U.S. Patent No. 6,889,694 to Hooven (hereafter “Hooven”), and that the prior rejections of claims 1-8, 10, 11, 13-18, 20, 22, 42 and 50-52 based in part on Hooven have been withdrawn.

II. Claims 38-43 and 47-49 are Novel Over Hooven

Independent claims 38 and 47 and respective dependent claims 39-43, 48 and 49 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Hooven. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicants respectfully submit the rejection is moot in view of the claims as amended.

Hooven fails to disclose, teach or suggest “a base member including a mating structure and defining a groove, the mating structure being configured for removably securing the base member to the first clamp member” as recited in claims 38 and 47. It is alleged in the Final Office Action that the jaw assembly 116 described by Hooven is the “first clamp member” as recited in claims 38 and 47, and the fixed insulator 122 described by Hooven is the “base member” as recited in claims 38 and 47. Applicants respectfully submit that the rejection based on Hooven cannot stand since the Final Office Action allegations are inconsistent with what is actually described by Hooven, and Hooven does not disclose, teach or suggest the structural configuration recited in claims 38 and 47.

Initially, it is alleged in the Final Office Action that that the fixed insulator 122 (the alleged “base member”) described by Hooven is “removably secured” to the fixed jaw assembly 116 (the alleged “first clamp member”). However, Hooven actually explains that the fixed insulator 122 is a component of the jaw assembly 116. More particularly, Hooven explains “The fixed jaw assembly 116 comprises a fixed electrode 120, a fixed insulator 122 and a fixed jaw cap 124.” Hooven (col. 11, lines 28-30). Consequently, the fixed insulator 122 cannot be a base member that is “removably secured” to the fixed jaw assembly 116, and cannot be “a base member including a mating structure and defining a groove, the mating structure being configured for removably securing the base member to a first clamp member” as recited in claims 38 and 47, since the fixed insulator 122 is a component the same jaw assembly 116. In other words, the Office Action essentially alleges that a component is releasably secured to a device that includes itself, which does not make sense and cannot support the rejection.

Additionally, Hooven does not disclose, teach or suggest that the fixed insulator 122 is removably secured to the fixed jaw assembly 116. Rather, FIG. 35 of Hooven shows unassembled components of the fixed jaw assembly. If the rejection stands, Applicants respectfully request the Examiner to identify by column / line number the section of Hooven that describes the fixed insulator 122 as being removably secured to the fixed jaw assembly 116 so that Applicants may better understand the basis of the rejection.

Moreover, the fixed insulator 122 (the alleged “base member”) is not “a base member including a mating structure and defining a groove, the mating structure being configured for removably securing the base member to a first clamp member” as recited in claims 38 and 47. It is alleged that the jaw assembly 116 described by Hooven is the “first clamp member” as recited in claims 38 and 47, and the fixed insulator 122 described by Hooven is the “base member” as recited in claims 38 and 47. However, Fig. 38 of Hooven shows the fixed insulator 120 (one component of the jaw assembly 116) interfacing with the fixed jaw cap 124 (another component of the jaw assembly). Therefore, the fixed insulator 120 does not have mating structure configured for removably securing the base member to a first clamp member since the fixed insulator 122 and the fixed jaw cap are components of the same jaw assembly 116.

Further, Hooven fails to disclose, teach or suggest “a coagulation element carried by the support member” and “a stimulation element carried by the support member” as recited in claim 38, and “means, carried by the support member, for transmitting coagulation energy to tissue” and “means, carried by the support member, for transmitting stimulation energy to tissue” as

recited in claim 47. Thus, as recited in the claims, the coagulation element and the stimulation element are carried by the same component, i.e., the support member.

It is alleged in the Final Office Action that that the fixed electrode 120 is a “support member” as recited in claims 38 and 47, a portion of the fixed electrode 120, i.e., the exposed portion, is a “coagulation element” (and apparently also a means for transmitting coagulation energy) as recited in respective 38 and 47, and the pair of bipolar pacing electrodes 172 is a “stimulation element” (and presumably a means for transmitting stimulation energy) as recited in respective claims 37 and 48. However, Hooven does not describe the fixed electrode 120 as having different components (a support member and, in addition, a coagulation electrode). Rather, Hooven simply refers to a fixed electrode 120.

Further, based on the claim limitations and the identification of components in the Office Action, the fixed electrode 120 would have to carry the coagulation electrode and, in addition, carry the pacing electrodes 172 since the claims recite that the coagulation and stimulation components are carried by the support member. However, Figs. 49 and 66 of Hooven show that the fixed electrode 120 does not carry the pacing electrodes 172. Rather, the fixed electrode 120 fills a groove in the insulator material (Hooven, col. 13, lines 66-67), and the pacing electrodes 172 are embedded within the jaw assembly 116. Therefore, pacing electrodes 172 are not carried by the fixed electrode 120. (Hooven, Fig. 66). Moreover, it would not make sense to have the fixed electrode 120 (the alleged “support member”) carry the pacing electrode 172 (the alleged “stimulation electrode”) since this results in two different types of electrodes (the fixed electrode 120 and the pacing electrode 172) being shorted or electrically connected to each other.

Accordingly, Applicants respectfully submit that the Office Action allegations are inconsistent with, and cannot be supported by, the components and structural configuration actually described by Hooven. Therefore, Applicants respectfully submit that independent claims 38 and 47 are novel over Hooven. Dependent claims 39-43, 48 and 49 incorporate the elements and limitations of respective independent claims 38 and 47 and, therefore, are also believed novel over Hooven.

Hooven also fails to disclose, teach or suggest “wherein the base member includes a mating structure configured to mate with the at least one of the first and second clamp members” as recited in claim 48. Rather, Fig. 38 of Hooven shows the fixed insulator 122 (the alleged base member, and one component of the jaw assembly 116) interfacing with the fixed jaw cap 124

(another component of the jaw assembly). Therefore, the fixed insulator 120 does not have mating structure configured for removably securing the base member to a first clamp member since the fixed insulator 122 and the fixed jaw cap are both components of the same jaw assembly 116. Clarification of the rejection is respectfully requested if the rejection stands following this amendment and response.

Moreover, Hooven fails to disclose, teach or suggest a base member including a mating structure configured to mate with the at least one of the first and second clamp members (as discussed above with respect to claim 48) and also including “a relatively narrow portion and a relative wide portion” as recited in claim 49.

Accordingly, Applicants respectfully request that the rejection of claims 38-43 and 47-49 under §102(e) be withdrawn.

III. Claim 45 Is Patentable Over Hooven

Dependent claim 45 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hooven. To establish *prima facie* obviousness of a claim, an initial requirement is that all of the claim limitations must be taught or suggested by the prior art. MPEP §2143.03. Further, there must be a reason to modify a reference as alleged in the Office Action. Applicants respectfully request that the rejection of dependent claim 45 under §103(a) be withdrawn in view of the deficiencies of Hooven discussed above with respect to independent claim 41.

Further, it is generally alleged that Hooven discloses “a second base member removable with the second clamp member, a second support member and a second coagulation element.” The Office Action refers to various columns and figures but does not identify which particular components correspond to the elements of claim 45. It is also generally alleged that it would be obvious to have pacing electrodes on a second jaw member. However, Hooven explains that when a pacing electrode is paired with the EKG sensor, the EKG sensors may be on “either side of the jaw, i.e., on either the pulmonary vein side or the atrial side of the ablation line created by the ablation electrodes.” Hooven (col. 15, lines 38-41) (emphasis added). Thus, Hooven describes the need for pacing electrodes 172 on one side, not two sides as alleged in the Office Action. Thus, an additional pair of pacing electrodes on a second clamp member is not an essential working part, contrary to what is alleged to support the rejection.

Accordingly, Applicants respectfully request that the rejection of claim 45 under §103(a) be withdrawn.

IV. Claims 1-8, 10, 11, 13-18, 20, 22 and 47-52 are Patentable Over Tetzlaff and Nezhat

Independent claims 1, 14, 38, 47 and 52 and respective dependent claims 2-8, 10, 11, 13, 15-18, 20, 22 and 48-51 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,277,117 to Tetzlaff *et al.* (hereafter “Tetzlaff”) in view of U.S. Patent No. 6,162,220 to Nezhat (hereafter “Nezhat”). To establish *prima facie* obviousness of a claim, all the claim limitations must be taught or suggested by the prior art, and there must be a reason to combine and/or modify the references. Applicants respectfully submit that the rejection is moot.

It is conceded that Tetzlaff fails to disclose “a stimulation element carried by the support member” as recited in claims 1 and 14 and “means, carried by the support member, for transmitting stimulation energy to tissue” as recited in claim 47. Final Office Action (p. 4).

Tetzlaff also fails to disclose, teach or suggest the structural combination of “a base member” that includes “a mating structure” and defines “a groove” and, in addition, “a support member, the groove formed within the base member being configured to receive the support member” as recited in claims 1, 14 and 47. It is alleged in the Office Action that the “base member” as recited in the claims is an electrically insulative substrate 111 described by Tetzlaff, and that the “support member” as recited in the claims is a collection of multiple components described by Tetzlaff: an interface 107, an opposing face 115, a seal surface 116, a wire crimp 119 and an extension 155. It is also alleged that the same seal surface 116 described by Tetzlaff is also a part of the “means for transmitting coagulation energy.” Thus, the seal surface 116 is alleged to be two different components: a part of the alleged support member and part of the alleged “means for transmitting coagulation energy.”

Accordingly, the basis of the rejection is not clear, but it is clear that no identified “support member” component is received within a groove defined within a base member. For example, the interface 107 is “located on conductive seal 116.” Tetzlaff (col. 7, lines 20-21). The opposing face 115 is part of the seal surface 116. Tetzlaff (col. 7, lines 12-13). The seal surface 116 is part of the electrode 110. Tetzlaff (col. 7, lines 1-2). The wire crimp 119 engages a distal end 91 of a prong 103. Tetzlaff (col. 7, lines 9-10). The extension 155 is part of the seal surface 116. Tetzlaff (col. 8-9). Figs. 5 and 7 of Tetzlaff further illustrate that there is no “support member” received within a groove defined within a “base member” as recited in claims

1, 14 and 47.

Tetzlaff also fails to disclose, teach or suggest “a coagulation element carried by the support member” that is received within a groove formed within the base member as recited in claims 1 and 14 and “means, carried by the support member, for transmitting coagulation energy to tissue” and that is received within a groove formed within the base member as recited in claim 47. Instead, Tetzlaff describes an electrode 110 that includes a seal surface 116 (part of the alleged support member and part of the alleged “means for transmitting coagulation energy”), which includes an opposing face 115 (another part of the “support member”) and a substrate 111 (the alleged “base member”). Thus, the basis of the rejection is not clear since the seal surface 116 is alleged to be two different components: “means for transmitting coagulation energy” and a component of the “support member.” Nevertheless, Tetzlaff does not disclose a coagulation element carried by a support member that is received within a groove defined within a base member as recited in the claims.

Nezhat is cited for the limited purpose of alleged disclosing a forceps device that includes coagulation elements and stimulation electrodes. Nezhat, however, does not cure the significant deficiencies of Tetzlaff and has its own deficiencies. Consequently, even assuming *arguendo* that the asserted combination of the references could be properly made, their combination would nevertheless fail to disclose each element of claims 1, 14 and 47.

Further, it is alleged that the tissue-penetrating elements 282, 284, 286 and 288 are “stimulation electrodes.” However, it is clear that tissue penetrating elements 282, 284, 286 and 288 are used for tissue penetration and application of radiofrequency energy for cutting and necrosing tissue. Nezhat (col. 1, lines 11-14; col. 4, lines 58-67). More specifically, the tissue stimulating elements are arranged for focusing application of RF energy for purposes of necrosing tissue. Nezhat (col. 6, lines 1-11; Fig. 3). Allegations that tissue stimulating elements arranged for focused application of RF energy to necrose tissue are “stimulation” elements ignores the accepted differences between “coagulation” and “stimulation” elements as is understood by persons skilled in the art and as recited in the claims.

In view of the above remarks, Applicants respectfully submit that the §103 rejection of independent claims 1, 14 and 47 cannot stand, and respectfully submit that independent claims 1, 14 and 47 are patentable over Tetzlaff and Nezhat, individually and in combination. Dependent claims 2-8, 10, 11, 13, 15-18, 20, 22 and 48-52 incorporate the elements and limitations of respective independent claims 1, 14 and 47 and, therefore, are also believed allowable.

The deficiencies of Tetzlaff and Nezhat, individually and in combination, with respect to claims 4, 6-8, 11, 13, 16-18, 22, 51 and 52 that recite a “simulation” element or a “stimulation” electrode are discussed above. Tissue penetrating elements 282, 284, 286, 288 described by Nezhat are not stimulation elements as recited in these claims since the tissue penetrating elements are used for the purpose of applying focused RF energy to tissue to necrose the tissue. Nezhat (col. 6, lines 1-11; Fig. 3).

The deficiencies of Tetzlaff and Nezhat, individually and in combination, with respect to claims 13, 22 and 52 are also discussed above.

Moreover, a person of ordinary skill in the art would not combine Tetzlaff and Nezhat given their different structural configurations and uses. Tetzlaff is directed to a device having flat, sealing surfaces for grasping and sealing a blood vessel. Tetzlaff (Figs. 8-11). Nezhat, on the other hand, describes a bipolar surgical device that includes tissue penetrating elements. Nezhat (col. 7, lines 15-17; Figs. 3A-B). Thus, the pointed tissue penetrating elements described by Nezhat have a structural configuration that is the opposite of the flat electrode surface described by Tetzlaff that is used to assure a uniform and quality seal. Tetzlaff (col. 1, lines 5-10; col. 9, lines 6-13).

Accordingly, Applicants respectfully request that the rejection of claims 1-8, 10, 11, 13-18, 20, 22 and 47-52 under §103(a) be withdrawn.

CONCLUSION

In view of the foregoing claim amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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